



CONGRESSIONAL HEARING RESUME

106th Congress
2nd Session

Date: 13 April 00

SUBJECT: Anthrax Vaccine Immunization Program

COMMITTEE: Senate Armed Services Committee,

CHAIRMAN: The Honorable John Warner, R-VA

THE FOLLOWING MEMBERS WERE PRESENT:

REPUBLICANS

**John Warner, VA
John McCain, AZ
Robert Smith, NH
James Inhofe, OK
Rick Santorum, PA
Olympia Snow, ME
Pat Roberts, KS
Wayne Allard, CO
Tim Hutchinson, AR
Jeff Sessions, AL**

DEMOCRATS

**Carl Levin, MI
Charles Robb, VA
Mary Landrieu, LA**

WITNESSES: See Attached

Information contained in this resume was obtained during an open hearing. It will not be released outside of the Department of Defense (DOD) agencies until published hearing transcripts have been released by the Committee, and only to the extent it is in accord with published hearing procedures.

Prepared by: Lt Col Brad Oswalt Date: 13 APR 00 Ext: 693-9110

WITNESSES

Panel One

Rear Admiral Lowell Jacoby, USN
Director, Intelligence Directorate
Office of the Joint Chiefs of Staff

Panel Two

Honorable Rudy DeLeon
Deputy Secretary of Defense

Honorable David Oliver
Principal Deputy
Undersecretary of Defense for Acquisition and Technology

Lt General Ronald Blanck, USA
Surgeon General of the Army

Maj Gen Randall West, USMC
Special Advisor to the Undersecretary of Defense
Personnel Readiness

Ms Carol Schuster
Associate Director
National Security Preparedness Issues
US General Accounting Office

EXECUTIVE SUMMARY

Senators aggressively questioned DoD witnesses about the threat, safety, and efficacy of the Anthrax Vaccination Immunization Program (AVIP). Overall, most Senators appeared grudgingly supportive. Sen Allard was definitive in his support--“no question, we should vaccinate.” Senators McCain and Snow were sympathetic to program opponents. Sen Snow specifically questioned DoD’s scientific evidence of safety and efficacy and pointed to conflicting studies that have been published. All Members stated they’ve received numerous calls from concerned constituents. Nobody questioned the severity of the threat, however there were numerous questions regarding the acquisition strategy for AVIP and why the DoD has only one source for such a critical vaccine. Sen Warner indicated the SASC plans on several more hearings on AVIP.

Opening Statements:

Chairman Warner

- Program is well on its way with over 400K personnel vaccinated
- Wants to focus on three areas: 1) the threat, 2) safety and efficacy, and 3) the acquisition approach
- Anthrax is highly lethal--“irrefutable”

Sen Levin:

- Many constituents are contacting his office
- Highlighted that all members of the Joint Chiefs of Staff said it was necessary, safe, and effective at Oct 99 hearings
- Feels there are conflicting views among scientific community

Sen Inhofe:

- Reluctantly supports program in the face of numerous constituent concerns, especially amongst the Guard and Reserve aircrew force

Sen Landrieu:

- Believes that although well-intentioned, not meeting SECDEF’s standards

Sen Allard:

- Highlighted his veterinarian background and his support of AVIP
- “No question--we should absolutely vaccinate”
- Anthrax exposure for our troops “scares the living daylights out of me”
- Did believe we should have two suppliers

PANEL 1: Provided overview of the threat. Level of threat was not questioned by SASC. Sen Inhofe did comment that the vaccine is impacting readiness and is especially damaging to Guard and Reserve personnel. He highlighted that 35 C-5 pilots at Travis and 68 pilots at McChord have refused the shot

Admiral Jacoby:

- Anthrax is #1 biological threat
- Equipment used to develop anthrax is “dual-use” and hard to detect
- Highlighted threat countries, especially IRAQ and North Korea
- Commented that anthrax is 100,000 times more lethal than chemical weapons

PANEL 2: Senators queried DoD and GAO witnesses in detail about the safety and efficacy of the program and the acquisition strategy

Mr. DeLeon:

- Program started with strong recommendation from Joint Chiefs of Staff
- DoD looked hard at the vaccine prior to initiating the AVIP
- Indicated that DoD consulted with FDA and received their support *prior* to initiation of the program
- Stated that the cost-benefit analysis still supports the AVIP due to the immensity of the threat

Lt Gen Blanck:

- Commented that all federal agencies consulted supported the AVIP, although formal support was limited to FDA with ad-hoc support from National Institute of Health and others

Ms Shuster, GAO:

- DoD's program is behind schedule and will run out of vaccine by July 00 unless additional lots of vaccine are approved by FDA
- DoD provided \$18M advance payment to help BioPort until FDA approval is received, but now further money is likely needed
- DoD has also provided a \$12M contract modification to hire consultants to assist in the FDA approval process
- Believes the hiring of consultants was appropriate to help ensure program success

Mr. Oliver:

- Explained DoD underestimated the problems involved in transferring BioPort from a state owned facility to a privately held firm
- DoD considered, but rejected, attempts to develop a second source because it was determined that it would take 7-10 years

Sen McCain:

- Asked GAO if the program needed additional testing
- GAO responded that additional testing would be beneficial, but would not make a recommendation on suspending the program
- Sen McCain said GAO was not doing its job if it couldn't make a recommendation
- Commented that Guard and Reserve units need to be better educated
- DoD has a perception problem among personnel and family members
- Not prepared to offer judgement, but too many personnel are concerned

Sen Allard:

- Highlighted significant animal testing has taken place and shows the vaccine is effective

Sen Roberts:

- Queried DoD about long-term plan beyond just BioPort
- Mr. DeLeon commented that we're working BioPort as the only short-term answer

Sen Snow:

- Doesn't believe the program has a strong scientific foundation
- More testing is necessary and commented that many expert studies refute DoD claims of safety and efficacy

Sen Allard:

- In regard to Sen Snow's comments, he stated that many "expert studies" are from questionable sources and requested DoD provide study data with bios on researchers
- Unscientific studies are not credible

Mr. DeLeon:

- DoD was not prepared for level of cyber activity on this program
- Personnel need to be cautious about points of view vs. points of fact on the Internet